REMARKS/ARGUMENTS

Applicants respectfully request entry of this amendment and reconsideration of this application. Submitted herewith is a Request for Continued Examination.

Applicants believe that the rejections made in the Office Action dated June 27, 2008 under 35 U.S.C. §102 and on the ground of non-statutory of obviousness-type double patenting have been withdrawn. Applicants thank the Office for the withdrawal of these objections.

By the amendments, Applicants do not acquiesce to the propriety of any of the Office's rejections and do not disclaim any subject matter to which Applicants are entitled. *Cf. Warner Jenkinson Co. v. Hilton-Davis Chem. Co.*, 41 U.S.P.Q.2d 1865 (U.S. 1997).

In the Claims

Claims 27-44 are pending in this application. Claim 1-26 were previously cancelled.

Claim 27 has been amended to recite that the microparticles specifically bind glycated albumin or total albumin in the sample. Support for this amendment can be found throughout the specification, for example in paragraph [0008]. Claim 27 has further been amended to indicate that the first and the second test strips contain bands associated with the solid support in a sequential arrangement and additionally each comprise a control band. Support for this amendment can be found throughout the specification, for example in paragraphs [0037] and [0040]. Claim 27 also now recites a solid support comprising a lateral flow membrane (support for example in paragraph [0044]) and that the application pad comprises a porous material to retain red blood cells from the sample in the application pad (support for example in paragraph [0045]).

Claims 28 and 29 have been cancelled.

Claims 32 and 35 have been amended to recite that the test strips each comprise a conjugate band, a test band and a control band. Support for this amendment can be found throughout the specification, for example in paragraphs [0037] and [0040].

Claim 44 has been amended to comport claim 44 to the amendments in claims 27, 32 and 35.

Applicants retain the right to pursue the subject matter of any cancelled or withdrawn claims in one or more related applications.

No new matter has been introduced as a result of the claim amendments.

35 U.S.C. §112 Rejections

Claims 27-44 have been rejected under 35 U.S.C. §112, second paragraph as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

The Office alleges that claim 27 is vague with regard to the phrase "which specifically being components of said sample." Claim 27 has been amended to recite "which specifically bind glycated albumin or total albumin in said sample."

The Office alleges that claims 28 and 29 are vague because they do not further limit the system of claim 27. Without acquiescing to the propriety of the Office's rejection, claims 28 and 29 have been cancelled.

35 U.S.C. §103 Rejections

I. Claim 27-39 and 44 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Yamamoto et al. in view of Chudzik et al. and Kang et al. Applicants respectfully disagree.

To maintain a proper rejection under 35 U.S.C. § 103, the Office must meet four conditions to establish a *prima facie* case of obviousness. First, the Office must show that the prior art suggested to those of ordinary skill in the art that they should make the claimed composition or device or carry out the claimed process. Second, the Office must show that the prior art would have provided one of ordinary skill in the art with a reasonable expectation of success. Both the suggestion and the reasonable expectation of success must be adequately founded in the prior art and not in an applicant's disclosure. Third, the prior art must teach or suggest all the claim limitations.

In re Vaeck, 20 U.S.P.Q.2d 1438, 1442 (Fed. Cir. 1991). Fourth, if an obviousness rejection is based on some combination of prior art references, the Office must show a suggestion, teaching, or motivation to combine the prior art references ("the TSM test"). *In re Dembiczak,* 50 U.S.P.Q.2d 1614, 1617 (Fed. Cir. 1999). Following *KSR Int'l Co. v. Teleflex, Inc.*, this fourth prong of the *prima facie* obviousness analysis must not be applied in a rigid or formulaic way such that it becomes inconsistent with the more flexible approach of *Graham v. John Deere*, 383 U.S. 1, 17-18 (1966); 127 S. Ct. 1727 (2007). It must still be applied, however, as the TSM test captures the important insight that "a patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art." *Id.* at 1741 (citing *United States v. Adams*, 383 U.S. 39, 50-52 (1966)).

Solely for the purpose of clarity and to expedite prosecution, and not to acquiesce to the propriety of any of the Office's rejections or statements, claim 27 has been amended to clarify that the claimed system comprises a solid support comprising a lateral flow membrane and a single application pad containing a sample well disposed on the solid support, wherein the application pad comprises a porous material to retain red blood cells in the application pad and wherein each test strip contains a control band.

Yamamoto discloses a "dry" test apparatus with two independent developing layers, each of which contain a position for sample application, a blood cell separating layer and a development initiation site. However, Applicants respectfully note that while Yamamoto calls the test apparatus "dry" it requires the addition of a developer defined in column 8, line 56 through column 9, line 6 as a buffer solution containing trace amounts of protein, a salt, a chelate compound, a surfactant and the like. A 0.1M phosphate buffer solution containing 0.1% bovine serum albumin, 0.9% sodium chloride, 0.01% EDTA, and 0.01% Triton X-100 was mentioned as a typical example of the developer. The presently claimed system does not require the addition of an exogenous developer.

Yamamoto does not disclose a solid support comprising a lateral flow membrane, a single application pad comprising a porous material to retain red blood cells or test strips comprising control bands.

Furthermore, the disclosure of Yamamoto is so unclear in the description of the claimed apparatus that it is difficult, if not impossible, to determine what the apparatus comprises. In column 2, line 51 through column 3, line 15 Yamamoto discloses:

> This and other objects of the present invention have been accomplished by a dry test apparatus for determining glycated albumin by simultaneously determining albumin and glycated albumin in whole blood by using a developer, which comprises:
>
> (A) a support having provided thereon a developing layer;
>
> (B) a blood cell-separating layer;
>
> (C) a reagent layer containing an albumin-staining dye (hereinafter often referred to dye 1) and a glycated albumin-staining dye (hereinafter often referred to dye 2);
>
> (D) a measuring layer having fixed thereto an albumin binding substance; and
>
> (E) a residual liquid absorbing layer which absorbs a residual developer,
>
> wherein said blood cell-separating layer, said reagent layer, said measuring layer, and said residual liquid absorbing layer are arranged sequentially on said developing layer (hereinafter referred to as a first embodiment).

Figures 1-4 of Yamamoto depict an apparatus having horizontal sequential regions of the test device devoted to various functions, while Figures 5 and 6 depict these same regions oriented as sequential vertical layers. Yamamoto does not define the term "layer", therefore a person of ordinary skill in the art must rely on the standard definition of layer which according to Merriam-Webster's online dictionary is "one thickness, course, or fold laid or lying over or under another" (http://www.merriam-webster.com/dictionary/layer). According to this definition, Figures 1-4 of Yamamoto do not depict layers. Accordingly, the figures and the description of Yamamoto are in conflict and are so unclear that a person of ordinary skill would not be able to determine what Yamamoto's apparatus is. Thus, Applicants respectfully assert that Yamamoto,

due to the lack of clarity and conflicting descriptions, does not teach or suggest, to a person of ordinary skill in the art, any component of Applicants' claimed invention.

Kang was cited for its teaching of the use of dyes or particles, such as colloidal metal particles or sol particles that are colored or colored polymeric particles to label immunoreagents on test strips (OA, page 4). Chudzik was cited for its teaching of the use of metal sols, dye sols or particulate latex as labels for tagging immunoreagents used on test strips (OA, page 4).

The combination of Yamamoto, Kang and Chudzik do not teach or suggest all the elements of the pending claims, specifically a system for detecting glycated albumin in a sample and determining the percent glycated albumin comprising a single application pad containing a sample well and comprised of a material which retains red blood cells, a first assay comprising a first test strip that measures glycated albumin and having a first control band, a second assay comprising a second test strip that measures total albumin in the same sample as the first assay and having a second control band; and means for calculating percent glycated albumin, wherein the first test strip and the second test strip include microparticles which specifically bind glycated albumin or total albumin in the sample.

Furthermore, persons of ordinary skill in the art understand that indicator particles cannot be simply substituted for indicator dyes due to the significant physical and chemical differences between the two materials. For example, it is well known to persons of ordinary skill that the flow of the indicator bound analyte through an immunochromatographic device is dependent on the size of the indicator-bound analyte complex and the porosity of the membrane strip. The size of the soluble dye complex taught by Yamamoto is several orders of magnitude smaller than the particle complexes taught by Kang and Chudzik. Therefore, even if Yamamoto, Kang and Chudzik disclosed all the elements of the claimed invention, either singly or in combination, which Applicants respectfully assert they do not, there is no expectation of success in achieving the claimed invention by combining the particles of Kang and Chudzik with the assay of Yamamoto.

In light of the claim amendments and arguments presented *supra*, Applicants respectfully assert that the Office has not established *prima facie* obviousness of claims 27, 30-39 and 44 over Yamamoto et al. in view of Chudzik et al. and Kang et al. The combination of Yamamoto, Chudzik and Kang does not teach all the limitations of the pending claims. Applicants respectfully request that this rejection be withdrawn.

II. Claim 40-43 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Yamamoto et al. in view of Chudzik et al and Kang et al and further in view of Galen et al. Applicants respectfully disagree.

As discussed *supra*, the combination of Yamamoto, Chudzik and Kang does not teach or suggest all the elements of independent claim 27, from which claims 40-43 depend. Galen was cited for teaching a reflectance spectrometer.

The teachings of Galen do not remedy the deficiencies of Yamamoto, Chudzik and Kang. The combination of Yamamoto, Chudzik, Kang and Galen do not teach or suggest all the elements of the pending claims, specifically a system for detecting glycated albumin in a sample and determining the percent glycated albumin comprising a single application pad containing a sample well and comprised of a material which retains red blood cells, a first assay comprising a first test strip that measures glycated albumin and having a first control band, a second assay comprising a second test strip that measures total albumin in the same sample as the first assay and having a second control band; and means for calculating percent glycated albumin, wherein the first test strip and the second test strip include microparticles which specifically bind glycated albumin or total albumin in the sample and wherein the means for calculating percent glycated albumin is a reflectance spectrometer or a fluorometer.

As a result of the claim amendments and arguments presented *supra*, Applicants respectfully assert that the Office has not established *prima facie* obviousness of claims 40-43 over Yamamoto et al. in view of Chudzik et al. and Kang et al and further in view of Galen et al. The combination of Yamamoto, Chudzik, Kang and Galen does not teach all the limitations of the pending claims. Applicants respectfully request that this rejection be withdrawn.

CONCLUSION

Applicants respectfully assert that, in light of the arguments and claim amendments presented herein, the claims are in condition for allowance and Applicant requests that a timely Notice of Allowance be issued in this case.

The Commissioner is authorized to charge any fee which may be required in connection with this Amendment to deposit account No. 50-3207.

Respectfully submitted,

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